UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

17

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,607	01/30/2001	Ib Jonassen	4409-214-US	2082

23650 7590 03/14/2007

NOVO NORDISK, INC.
PATENT DEPARTMENT
100 COLLEGE ROAD WEST
PRINCETON, NJ 08540

EXAMINER	
KAM, CHIH MIN	
ART UNIT	**PAPER NUMBER**
1656	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/772,607	JONASSEN ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48-55 and 57-59* is/are rejected.

7)☒ Claim(s) *56* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Request for Continued Examination (RCE) filed on December 21, 2006 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

Status of the Claims

2. Claims 48-59 are pending.

Applicants' response filed December 21, 2006 is acknowledged and has been fully considered. Thus, claims 48-59 are examined.

Withdrawn Claim Rejections - 35 USC § 102

3. The previous rejection of claims 48 and 49 under 35 U.S.C. 102(b) as being anticipated by Habener (U.S. Patent 5,118,666), is withdrawn in view of applicant's response at pages 7-8 in the amendment filed December 21, 2006.

Maintained Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 48-55 and 57-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-7 and 15 of co-

pending application 09/757,788 (published as US 2001/0012829) based on the amendment filed December 21, 2006. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 48-55 and 57-59 in the instant application disclose a derivative of GLP-1 or an analog thereof having a lipophilic substituent which contains 8 to 40 carbon atoms, optionally has an amino group, and is attached to the C-terminal amino acid of GLP-1 or analog thereof optionally via a spacer, wherein the spacer is Lys, Glu, Asp, Glu-Lys or Asp-Lys; and the specification of the instant application discloses a pharmaceutical composition comprising the derivative of GLP-1 or an analog thereof and a carrier, which can be used for nasal administration (page 7, line 5-37). This is obvious in view of claims 1-3, 5-7 and 15 of the co-pending application which disclose a formulation suitable for pulmonary administration to a subject, said formulation comprising a GLP-1 compound having attached thereto a lipophilic substituent comprising 14-18 carbon atoms optionally via spacer, wherein the formulation upon nebulization achieves a mass medium aerodynamic diameter of less than 10 μm; and the specification indicates a lipophilic substituent can be attached to the carboxyl group attached to the alpha-carbon of the C-terminal amino acid (paragraph [0192]). Since the co-pending application discloses a formulation comprising a GLP-1 compound having a lipophilic substituent comprising 14-18 carbon atoms, which can be attached to the C-terminus of the GLP-1 compound optionally via a spacer, and these GLP-1 compounds are also encompassed by the claims of the instant application, thus, both sets of claims encompass a derivative of GLP-1 having a lipophilic substituent comprising 14-18 carbon atoms, which can be attached to the C-terminus of the GLP-1 compound optionally via a spacer. Therefore, claims 48-55 and 57-59 in instant application and claims 1-3, 5-7 and 15 of the co-pending application are obvious

variations of a derivative of GLP-1 or an analog thereof having a lipophilic substituent comprising 14-18 carbon atoms, which can be attached to the C-terminus of the GLP-1 compound optionally via a spacer, and the GLP-1 derivative can be prepared in a formulation for pulmonary administration.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants present a side by side comparison of the limitations of independent claim 48 of the present application with the limitations of independent claim 1 of the '788 application. Applicants indicate the claims in the present application are to GLP-1 derivatives and not to formulations of any kind. By comparison, the claims in the '788 application are to liquid formulations suitable for pulmonary administration where such formulations contain GLP-1 compounds. Thus, the claims in both applications are not directed to formulations. Applicants also indicate that the Examiner has provided no reasoning for why the GLP-1 compound contained in the liquid formulations claimed in the 788 application (i.e., a GLP-I compound which has a lipophilic substituent of 14-18 carbon atoms attached to any AA of the GLP-1 compound) would render obvious a GLP-I derivative in which a lipophilic substituent of 8-40 carbon atoms is attached to the C-terminal AA of the GLP-1 or analog thereof. Applicants further assert that the Examiner's reliance on the disclosure in the specification of the present application of nasal formulations is improper and misplaced and does not provide any reason for why a person of ordinary skill in the art would conclude that the invention defined in claims 48-55 and 57-59 of the present application would be an obvious variation of the invention defined in

claims 1-3, 5-7 and 15 of the cited '788 application. Accordingly, the claims of the present application are not obvious over the claims in application 09/757,788 and withdrawal of this rejection is requested (pages 4-6 of the response).

Applicants' response has been fully considered. However, the argument is not found fully persuasive because of the following reasons. As indicated by applicants' comparison, while claim 1 of the co-pending application claims a formulation suitable for pulmonary administration to a subject, the formulation comprising a GLP-1 compound having attached thereto a lipophilic substituent comprising 14-18 carbon atoms optionally via spacer, wherein the formulation upon nebulization achieves a mass medium aerodynamic diameter of less than 10 μm, the formulation is prepared from the GLP-1 compound, and the specification of co-pending application indicates a lipophilic substituent can be attached to the carboxyl group attached to the alpha-carbon of the C-terminal amino acid (paragraph [0192]), thus the claim of copending application encompasses a GLP-1 compound having a lipophilic substituent comprising 14-18 carbon atoms, which can be attached to the C-terminus of the GLP-1 compound, and this GLP-1 derivative can be used in a formulation for pulmonary administration. Thus, the GLP-1 derivative cited in the claim of the co-pending application is clearly encompassed by the GLP-1 derivative of claim 48 which has a lipophilic substituent containing 8 to 40 carbon atoms, optionally has an amino group, and is attached to the C-terminal amino acid of GLP-1 optionally via a spacer. Therefore, both sets of claims are obvious variations of a derivative of GLP-1 or an analog thereof having a lipophilic substituent comprising 14-18 carbon atoms, which can be attached to the C-terminus of the GLP-1 compound optionally via a spacer, where the derivative of GLP-1 can be in a formulation.

New Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Habener (U.S. Patent 5,118,666, publication date: June 2, 1992).

Habener teaches a GLP-1 derivative having a formula H_2N-X-CO-R^1, where X is the peptide comprising the sequence His-Ala-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Val-Ser-Ser-Tyr-Leu-Glu-Gly-Gln-Ala-Ala-Lys-Glu-Phe-Ile-Ala-Trp-Leu-Val-Lys-Arg; R^1 is OH, OM or $-NR^2R^3$; and M is a pharmaceutically acceptable cation or a lower branched or unbranched alkyl group; R^2 and R^3 are hydrogen or a lower branched or unbranched alkyl group (column 3, lines 6-46). While the GLP-1 derivative with a lower alkyl group such as C_{1-6} attached to its C-terminus is prepared, it is obvious that alkyl group greater than C_6 can be used to attach to the C-terminus amino acid of GLP-1 peptide (claims 48 and 49).

Claim Objection

6. Claim 56 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusions

7. Claims 48-55 and 57-59 are rejected, and claim 56 is objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner

CHIH-MIN KAM
PRIMARY EXAMINER

CMK
March 12, 2007